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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,310	01/09/2001	Pierre Jean Francois Layrolle	04148-00006	7859

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EXAMINER

LAMB, BRENDA A

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 03/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,310

Applicant(s)

Layrolle et al

Examiner

LAMB

Group Art Unit

1734

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/16/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 26-46 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 26-46 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims ~~24~~-28, 30-32 and 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of either of Dunn or Zebulske.

Benoit et al teaches the design of coating apparatus having a reactor vessel R-2, heating element TC, stirrer, a plurality of inlets/outlets connected to the reactor and a controlled source of carbon dioxide operatively connected to an inlet (see column 11, lines 1-53 and Figure 1). Benoit et al fails to teach an implant support and end use of coating apparatus for coating an implant. However, it would have been obvious to modify the Benoit et al apparatus by providing a support for the implant which is operatively connected to the vessel since it is conventional to operatively connect to a coating/reactor vessel a support for an article being treated such as a support for tablets or granular material which is external to the reactor such as the container and

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discharge piping which receives the coated material from the coater vessel such as taught by Dunn or an inner support within the reactor, an open inner container, for the granular material within the reactor vessel such as Zebulske for the obvious reason to provide greater control for the coating process. Note Dunn shows an implant support includes a hooked or curved surface discharge outlet supporting the coated granular material thereby reading on a hook. Finally, it is noted that Benoit et al fails to teach the end use of his apparatus to coat implants. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The Benoit et al apparatus as modified is capable of coating implants. Finally the recitation of an aperture to avoid increasing internal pressure of the reactor vessel does not further limit applicant's invention over Benoit et al in that Benoit et al has a plurality of aperture or openings which include drain valve (drain) which as depicted drains contents from the reactor vessel R-2 and exhaust valve to atmosphere and each of these valves is obviously configured to avoid increasing internal pressure of the reaction by draining/exhausting the contents of the reactor. With respect to claims 27-28, Benoit teaches the stirrer is magnetic transmission stirrer and obvious the stirrer is capable of being controlled such that stirrer rotates at 100 rpm given the wide range of agitation speeds set forth in the Examples 1-25. With respect to claims 30-31, Benoit et al teaches valve V-2 to control flow of carbon dioxide to the reaction vessel. Although Benoit et al fails to teach the valve is a solenoid valve or an electro valve, it would have been obvious to use any conventional type of valve as valve (v-2) in the Benoit apparatus including a solenoid or electro-valve for the obvious advantage over manual control valves. With respect to claim 35-

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36, Benoit et al teaches in the examples that, volume/capacity of the reactor vessel/autoclave is 1.5 liters. With respect to claims 37 and 39, Benoit et al teaches at column 11, lines 48-53 teaches that reservoir or reactor vessel is equipped with separate cooling and heating jacket (TC) or is double jacketed as shown in Figure 1 to obtain various temperatures. Benoit et al also teaches in examples 1-25 that the temperature of the reaction vessel/ autoclave is within the scope of the claims. With respect to claim 38, Benoit et al teaches at column 11, lines 13-25 fluid can be heated prior to circulation of the fluid to reactor vessel/ reservoir/ autoclave and heating of the fluids prior to recirculation of the fluids to the reactor thereby reads on a thermocirculator. With respect to claims 41 and 42, Benoit et al teaches that pressure and temperature within the reaction vessel/autoclave is adjusted in a controlled manner (see column 8, line 59 to column 9, line 52). Benoit et al fails to teach an automated system for controlling temperature and pressure as a function of time but obvious to do so for the advantage of automation of a process step of measure and controlling process conditions. With respect to claims 43-44, Benoit et al teaches at column 11, line 53 filtering devices are associated with Benoit coating apparatus but fails to teach the filtering device a membrane filter has pore size of 0.2 mm. However, it would have been obvious to provide as the filtering device in the Benoit et al apparatus a conventional filtering device, a filter membrane cell, optimizing pore size of the membrane cell such that are within the scope of the claim dependent on end use of apparatus. With respect to claim 32, the recitation of electrode operatively connected to reactor/autoclave does not define applicant's invention over Benoit et al since it would have been obvious to include an electrode in Benoit et al since conventional to measure result effect process parameters in a reactor such as pH using a conventional pH measuring means, an electrode.

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With respect to claim 45, the same rejection applied to claims 1, 27, 39, 30 and 32 is applied here. With respect to claim 46, same rejection applied to claim 45 is applied here. Benoit et al teaches as discussed above temperature and pressure vessel/autoclave is adjusted in a controlled manner (See column 8, line 59 to column 9 line 24). Benoit et al fails to teach an automated system for controlling temperature and pressure as a function of time but obvious to do so for advantage of automation of a process step of measuring and controlling process conditions.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Roberto and either Dunn or Zebulske.

Benoit et al, Dunn and Zebulske are applied for the reasons noted above Benoit et al fails to disclose the reactor vessel includes a coating to avoid deposition or incrustation of carbonate and calcium phosphate or is fashioned from stainless steel. However, Roberto providing a lining of polytetrafluoroethylene on a metal reaction vessel which is conventionally a stainless steel material to provide greater corrosion resistance of the reaction vessel. Therefore, it would have been obvious to provide in the Benoit et al reaction vessel with a polytetrafluoroethylene lining such as taught by Roberto et al for the taught advantage of the polytetrafluoroethylene coated metal vessel-increased resistance to corrosion. The recitation that the coating avoids deposition or incrustation of carbonated calcium phosphate does not define applicant's invention over Benoit et al as modified above since the Roberto polytetrafluoroethylene coating is within the scope of coating disclosed by applicant in the instant specification.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benoit et al in view of Roberts et al, Wheeler et al and either Dunn or Zebulske.

Benoit et al fails to teach a porous sparger. However, it would have been obvious to use any conventional means to introduce carbon dioxide into the Benoit et al reactor vessel by providing a porous sparger since it is conventional to introduce gaseous components into a reactor using a sparger to more thoroughly disperse the gaseous component in a vessel and obvious to use a sparger producing microbubbles by the porous sparger as taught by Wheeler et al for obvious advantage of greater dispersal within the liquid.

Applicant's arguments filed 12/16/02 have been fully considered but they are not persuasive.

Applicant's argument that applicant's invention define over Benoit et al in that his aperture is not a switchable mechanism is found to be non-persuasive since the aperture does not exclude the use of valve within the aperture.

Applicant's argument that Benoit et al fails to teach or implant support is found to be non-persuasive since the recitation of an implant support operatively associated with the reactor vessel is so broad that it includes a support for tablets or granular material which is external to the reactor such as the container which receives the coated from the coater vessel such as taught by Dunn or inner support, an open inner container, for the granular material within the reactor vessel such as Zebulske.

Applicant's argument that Benoit et al fails to teach an implant support which are special hooks fixed on the head-plate of the bioreactor is found to non-persuasive since it is not commensurate in scope with the claim limitations.

Applicant's argument of the non-obviousness of using the Benoit et al apparatus to coat implants is found to be non-persuasive. It has been held that a recitation with respect to the

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manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Applicant's argument that Benoit et al fails to teach the use of an autoclave having the capacity of other than 1.5 liters is found to be non-persuasive. It is noted that the Benoit et al reactor capacity of 1.5 liters is within the scope of claimed range of the reactor capacity set forth in claims 35-36.

Applicant's argument that Benoit et al fails to teach a thermocirculator as set forth on page 10 lines 35-36 of the instant specification is found to be non-persuasive. It is noted that applicant has claimed a thermo-circulator but has failed to claim the function of the thermocirculator and its relationship to the other elements of the apparatus. Therefore, the examiner maintains that Benoit et al teaches at column 11, lines 13-25 fluids can be heated prior to circulation of the fluid to reactor vessel/ reservoir/ autoclave and heating as recirculating of fluids to the reactor thereby reads on a thermocirculator.

Applicant's argument of the non-obviousness of using substituting Benoit et al standard valve with a solenoid or electrovalve is found to be non-persuasive. Benoit et al fails to teach his valves are standard valves as argued by applicant. The examiner maintains that although Benoit et al fails to teach the valve is a solenoid valve or an electro-valve, it would have been obvious to use any conventional type of valve as valve (v-2) in the Benoit apparatus including a solenoid or electro-valve for the obvious advantage over manual control valves.

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Any inquiry concerning this communication should be directed to Brenda Lamb at telephone number 703 308-2056. The examiner can normally be reached on Monday and Wednesday through Friday with alternate Tuesdays off.

B.A. Lamb/dh

March 12, 2003

Brenda Adele Lamb

BRENDA A. LAMB
PRIMARY EXAMINER
~~GROUP 1300~~